 K101693

510(K) SUMMARY

JAN - 5 2011

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.0 Submitter's Information

Establishment Registration Name:

Foshan Gaunying Electronics Co., Ltd.

4F, #4 Industry Country,
Cheng Nan Park of Foshan Hi-tech Industrial Development Zone
Foshan, Guangdong, China 528000

Contact Person (US Agent/Official Correspondent) of the Applicant:

Mr. Guenter Ginsberg
(President)

Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135, USA
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Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Infrared Lamp
Trade Name:	Infrared Lamp
Model:	IL50
Classification name:	lamp, infrared, therapeutic heating
Review Panel:	Physical Medicine
Product Code:	ILY
Regulation Class:	Class II
Regulation Number:	21CFR 890.5500

K101693

2.0 Predicate Device Information

Sponsor:	Chongqing Xinfeng Medical Instrument Co., Ltd.
Device:	Xinfeng Heating Lamp, including 3 different models CQ-27, CQ-36 and CQ-55A
510(K) Number:	K043558

3.0 Device description

Gaunying Infrared Lamp (Model#: IL50) has a high-quality glass ceramic plate (ceramic infrared). Glass ceramic plates are also used on hobs and when used in conjunction with illuminants guarantee intensive and safe infrared radiation.

4.0 Intended Use

The Gaunying Infrared Lamp (Model #: IL50) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, or muscle spasm; the temporary increase in local blood circulation.

5.0 Performance Summary

Testing of the Infrared Lamp (Model#: IL50) includes functional performance testing and electrical safety testing. The device is manufactured to comply with the following international standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)). (General)
- UL 60601-1, first edition, 2003, deviations to IEC 60601-1
- **Performance Bench Tests:**
  Two (2) devices were tested for heat output at distances of 30, 35 and 40cm from the infrared source. Temperatures were recorded every one (1) minute, up to 15 minutes, using a digital temperature sensor. The test results concluded that the Infrared Lamp (Model#: IL50) was able to maintain temperatures above 40° C (the desired effective temperature) at least 10 minutes of the 15 minutes cycle time. The tests also showed that the temperature at the sensor (skin) never exceeded a temperature of 45° C. Both devices used for this test tracked each near 100%.

K101693

Usability Test:
A group of 10 people were selected, 5 females and 5 men with different ages and educational backgrounds. They were given the Operating Instructions (OI) to read and study before using the subject device. The test group had no problem operating the device, but had questions and clarifications about some statements in the OI. The OI was changed accordingly. A new study group of 10 people were tested and observed. Nobody had any difficulties understanding the OI and operating the device. It was concluded that the Operating Instructions are clear and have enough information and warnings that lay people should not have any difficulties understanding the instructions and operating the device safely and effectively.

6.0 Comparison to predicate device and conclusion

Compared with predicate device Xinfeng CQ-27, CQ-36 and CQ-55A Heating Lamps made by Chongqing Xinfeng Medical Instrument Co., Ltd. (K043558), the device Infrared Lamp (Model#: IL50) has same intended use with the predicate device. Although, there is a little different technological characteristics;

The infrared wavelength used in subject device and predicate device is deferent. The subject device uses 600 nm — 2000 nm infrared, which belongs to Near-infrared (0.75-1.4 μm) and Short-wavelength infrared (1.4-3 μm). The predicate device use 5 to 25 microns, which belongs to Long-wavelength infrared (8–15 μm) and far infrared (15-1,000 μm).

The human visible light is in wavelength 400–700 nm. So the subject device heating can be seen when it is working. The predicate device heating is not visible when it is working. That means the possibility of burns risk for subject device is less than the predicate device.

Comparison Temperature Test:
A bench test was set up to compare the heat output of the predicate device with the subject device. Temperatures were recorded for both devices at distances of 30, 35, and 40 cm and at 1 minute intervals up to 55 minutes. The results show that the Gaunying Infrared Lamp (the subject) tracks the temperature readings of the Xingfing Heating Lamp (the predicate device) and is therefore equivalent in performance to the predicate device.

Whatever Near-infrared, Short-wavelength infrared, Long-wavelength infrared and Far infrared, they all can heat and therapy disease. The different wavelength will not affect the effectiveness of device. The testing report shows that Infrared

K101693

Lamp (Model#: IL50) is as safe and effective as the predicate device.

So, the difference does not raise new questions of safety and effectiveness. The Infrared Lamp (Model#: IL50), is substantially equivalent to the predicate device.

7.0 Submission date:

June 16, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Foshan Gaunying Electronics Co., Ltd.
% Media Trade Corporation
Mr. Guenter Ginsberg
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

JAN - 5 2011

Re: K101693
Trade/Device Name: Gaunying Infrared Lamp, Model IL50
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: December 10, 2010
Received: December 10, 2010

Dear Mr. Ginsberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K101693

Device Name: Gaunying Infrared Lamp
Model: IL50

JAN - 5 2011

Indications For Use:

The Gaunying Infrared Lamp (Model #: IL50) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, or muscle spasm; the temporary increase in local blood circulation.

Prescription Use ___ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101693

Page _1_ of __1_